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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/779,237	02/08/2001	Frederik Coenraad Botha	P-6149	2105

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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/779,237	Applicant(s) BOTH A ET AL.	
	Examiner Russell Kallis	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6,7,9,12 and 15-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,9,12 and 15-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/25/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/14/2003 has been entered.

Claims 1-4, 6, 8-9, 12, 15-18 and 20-28 are pending.

The rejection of Claims 1-4, 6, 8-9, 12, 15-18 under 35 U.S.C. 112, first paragraph, written description is withdrawn in view of Applicant's amendments and arguments.

Claim Objections

Claim 24 is objected to because of the following informalities: In line 1, "call" should be "cell". Appropriate correction is required.

Specification

The disclosure, e.g. on page 7, is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-4, 6, 8-9, 12, 15-18 and 20-28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, is enabling only for claims limited to the isolated sugarcane PFP nucleotide sequences of SEQ ID NO: 1 and SEQ ID NO: 2, a method of down regulating the total activity of the PFP enzyme in a plant by transformation with a plant expression vector comprising either a sense or an antisense version of SEQ ID NO: 2 encoding the PFP- β subunit from sugarcane or sense portions of SEQ ID NO: 2, such as the exemplified 1170 bp sense portion of SEQ ID NO: 1, such that sucrose content is increased. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/23/02 and 3/14/2003. Applicants arguments filed 8/14/2003 have been considered but are not deemed persuasive.

Applicant claims a method of regulating and manipulating sucrose content in a sugar storing plant by regulating the activity of the PFP enzyme in the plant by transformation with a plant expression vector comprising either an untranslatable sense or an antisense polynucleotide or fragment thereof encoding a PFP enzyme subunit such that sucrose content is increased.

Applicant teaches cloning and characterization of a full length sugarcane PFP- β cDNA of SEQ ID NO: 2 using degenerate PCR primers based upon the castor bean and potato sequences for PFP- β to make a sugarcane probe to probe a sugarcane cDNA library (page 7, lines 13-24), construction of plant expression vectors comprising an untranslatable sense or antisense version of SEQ ID NO: 1, (a 1170 b.p. fragment of SEQ ID NO: 2), the maize polyubiquitin UBI

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promoter, and the CaMV 35S promoter (page 8, lines 5-18), and transformation and identification by PCR analysis of sugarcane transformed with a vector comprising the sense construct PFP- β (page 8, lines 20-33, page 9, lines 1-16). Applicant teaches that the transformed plants have decreased total activity of the PFP enzyme and sucrose content is increased (page 10, Table 1).

Applicant does not teach the cloning and characterization of PFP cDNA, fragments, variants from sugar storing plants other than PFP- β from sugarcane, the construction of plant expression vectors that comprise PFP cDNA fragments or variants from other sugar storing plants, transformation of sugar storing plants, or down regulation of the total activity of the PFP enzyme in sugar storing plants by transformation with a plant expression vector comprising either an untranslatable sense or an antisense polynucleotide encoding the PFP subunit from a target plant other than sugarcane such that sucrose content is increased; or reasonably provide enablement for methods other than transformation with a plant expression vector comprising a sugarcane PFP in sense orientation, such as methods using chemicals other than DNA to affect sucrose metabolism, a method using PFP sequences from other species or DNA sequences other than PFP that could also down regulate expression of a PFP enzyme, or down regulation of PFP in other sugar storing plants. Furthermore, the specification does not reasonably provide enablement for portions or variants of sugarcane PFP cDNA or other PFP sequences from other species of plants.

Applicant asserts that the portions recited in the claims are enabled because one of skill in the art could make and test the portions for their ability to either up regulate or down regulate the activity of the endogenous PFP gene in sugar cane (response page 11). Applicant has not

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exemplified a fragment that would either up regulate or down regulate activity or do both. It is not clear how a fragment that would up regulate activity would also down regulate activity as well. Further, Applicant's assertions that the amount of experimentation required to enable portions or fragments of a PFP gene either in sense or antisense orientation is not undue experimentation (response pages 12-14) only highlights the point that Applicant has not taught how to make or use fragments that would either up regulate or down regulate PFP expression in a plant or how to make or use a fragment that would up regulate or down regulate expression when in either sense or antisense orientation. Furthermore, Applicant's asserts that the prior art supports the claim to enablement of portions of the PFP gene (response pages 14-15). Applicant has submitted references to support the use of fragments for antisense or sense suppression, most of which were published after the effective filing date of 2/4/2000 and do not teach the use of a PFP gene for antisense or sense suppression. Since a disclosure must be complete as of the filing date, subsequent publications or subsequently filed applications cannot be relied on to establish a constructive reduction to practice or an enabling disclosure as of the filing date. *White Consol. Indus., Inc. v. Vega Servo-Control Inc.*, 713 F.2d 788, 218 USPQ 298(CCPA) 1974); *in re Glass*, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974).

The unpredictability of Applicant's admission is increased when the sequences of the claimed methods and plants comprising said sequences require undue experimentation to isolate and identify other non-exemplified PFP nucleic acids, or non-exemplified portions thereof, or non-exemplified untranslatable forms that are effective in the claimed methods.

Moreover, the power of discrimination of an antisense portions or fragments of at least 50 nucleotides in length is unpredictable because the mechanism of RNA knockout by antisense is

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sensitive to a short hybrid region as small as 10 base pairs or less of an RNA-RNA duplex for cleaving mRNA. Increases in size beyond this minimum region will not necessarily inhibit duplex formation, but may act to stabilize the structure, and thus the specificity of a short RNA fragment is dependent upon complex and unpredictable factors and will read on and eliminate messages other than that of its endogenous source and target. Branch A.D. TIBS, February 1998, pages 45-50; page 47 column 3.

Claims 15 and 16 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official actions mailed 7/23/02 and 3/14/2003. Applicants arguments filed 8/14/2003 have been considered but are not deemed persuasive.

Applicant asserts that they have met the requirements of 37 CFR 1.801-1.809 (response pages 15-16). The rejection is maintained since the South African Sugar Association is not listed in the MPEP as an IDA and because it is not clear that the South African Sugar Association has been recognized as suitable by the Commissioner which is a requirement as indicated 37 CFR 1.803.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-4, 6, 8, 9, 12, 17-18, 21-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claim 1 and throughout the claims the use of the term ‘gene’ is indefinite because ‘gene’ encompasses promoter, intron, exons and termination signals and can refer to either coding or non-coding regions as well as regulatory regions of DNA.

In Claim 6, “capable of” is indefinite. It is unclear whether it can or cannot up regulate or down regulate PFP enzyme activity.

In Claim 9, “directly” is indefinite. It is not clear whether the placement is adjacent or anywhere downstream.

In Claims 20, 22, 23 and 24 the claimed plant cell or part is being compared to a whole untransformed plant.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
April 29, 2004


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER